

REMARKS

The present Amendment is in response to the Office Action mailed July 1, 2004 in the above-identified application.

The Examiner objected to the drawings because there are two figures labeled "FIG. 18." In response, Applicants enclose herewith a new drawing sheet 11 of 23 that changes the figure labeled "FIG. 18" to --FIG. 16--.

Applicants acknowledge that claims 11, 19 and 44-47 have been withdrawn from further consideration in the present application, subject to Applicants' right to file the claims in a continuing or divisional application. In the present Amendment, claims 9, 11, 19, and 44-47 have been canceled.

The Examiner objected to claim 1 because the term "transverse" is used. In response, claim 1 has been amended to change "transverse" to --intersect--. Applicants note that there is no requirement that the first and second longitudinal axes recited in claim 1 intersect one another at right angles.

The Examiner rejected claims 1-3, 5-10, 12, 15-17, 20, 28-32, 34-35 and 42-43 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,891,145 to Morrison et al. The Examiner asserts that Morrison teaches a coupling element having a first opening at an upper end and a second opening at a lower end, whereby the first and second openings have respective central axes that are angled relative to one another. In FIGS. 1 and 2 thereof, Morrison shows a multi-axial assembly 10 including a threaded bone screw 20 and a receiver member 30. As shown most clearly in FIG. 2, the multi-axial assembly 10 includes an outer wedge member 40 in contact with an inner surface of the receiver member 30 and an inner wedge member 50 that fits within the outer wedge member 40. As shown in FIGS.

6B and 8B, the outer and inner wedge members 40, 50 have inclined bores extending therethrough. During assembly, outer wedge member 40 is first positioned inside receiver member 30 (in contact with the inner surface of the receiver member) and then inner wedge member 50 is placed inside the bore extending through the outer wedge member 40. The bone screw 20 is then passed through the bore of inner wedge member 50. After the components are in place, a surgeon may form various angles between the bone screw 20 and the receiver member 30 by rotating outer and inner wedge members 40, 50 with respect to each other and with respect to receiver member 30. When a desired angle has been achieved, a force may be placed atop head portion 22 of bone screw 20 for locking the bone screw 20 from further movement relative to the receiver member 30.

In response to the Examiner's Section 102(b) rejection, Applicants have slightly amended independent claims 1, 28 and 42 to more clearly distinguish over the Morrison reference. Specifically, the head of Morrison's bone screw does not contact the inner surface of the receiver member 30. In contrast, the head of the bone screw in the present application comes in direct contact with the inner surface of the coupling element. As amended, independent claim 1 is unanticipated by Morrison because the cited reference neither discloses nor suggests a bone fixation assembly including "a coupling element having an inner surface defining a first bore coaxial with a first longitudinal axis and a second bore coaxial with a second longitudinal axis, . . . said coupling element including a seat adjacent said lower end of said coupling element, said seat being defined by the inner surface of said coupling element; and an anchoring element [having a] head being in contact with said seat of said coupling element." Clearly, the head of Morrison's bone screw 20 never comes in contact with the inner surface of

receiver member 30, or a seat defined by the inner surface of the receiver member. As shown in FIGS. 1 and 2 thereof, the head of Morrison's bone screw is spaced from an inner surface of receiver member 30 by inner wedge member 50 and outer wedge member 40. As a result, Morrison's head never comes "in contact with said seat of said coupling element" as required by claim 1. For these reasons, claim 1 is unanticipated by Morrison and is otherwise allowable. Claims 2-3, 5-10, 12, 15-16 and 20 are unanticipated, *inter alia*, by virtue of their dependence from claim 1, which is unanticipated for the reasons set forth above.

Amended claim 28 is unanticipated by Morrison for generally the same reasons discussed above with respect to claim 1. Specifically, amended claim 28 is unanticipated by Morrison because the cited reference neither discloses nor suggests a coupling element having an upper end and a lower end, "said coupling element having an inner surface defining said first and second bores and a seat adjacent said second bore at said lower end of said coupling element; and an anchoring element having a first end for insertion into bone and a head spaced from said first end, said head being in contact with said seat of said coupling element." As noted above, the head of Morrison's bone screw 20 (FIG. 2) is spaced from the inner surface of receiver member 30 by inner wedge member 50 and outer wedge member 40 (FIG. 2). Morrison does not teach that the head is in direct contact with a seat defined by "an inner surface" of the coupling element. For these reasons, independent claim 28 is unanticipated by Morrison and is otherwise allowable. Claims 29-32 and 34-35 are unanticipated, *inter alia*, by virtue of their dependence from claim 28, which is unanticipated for the reasons set forth above.

Independent claim 42, as amended, is unanticipated by Morrison because the cited reference neither discloses nor

suggests a coupling element "including an inner surface having a first section at an upper end of said coupling element, said first section defining a first bore extending through said coupling element that is coaxial with a first longitudinal axis [and] the inner surface having a second section at a lower end of said coupling element, said second section defining a second bore extending through said coupling element that is coaxial with a second longitudinal axis, wherein said first and second longitudinal axes intersect one another." Referring to FIG. 2 thereof, Morrison's receiver member 30 does not have an inner surface "defining a second bore extending through said coupling element that is coaxial with a second longitudinal axis, wherein said first and second longitudinal axes intersect one another." Morrison's second bore is defined by an inner surface of inner wedge member 50. The second bore is not defined by the inner surface of the receiver member 30, as required by claim 42. For these reasons, claim 42 is unanticipated by Morrison and is otherwise allowable. Claim 43 is unanticipated, *inter alia*, by virtue of its dependence from claim 42, which is unanticipated for the reasons set forth above.

In the Office Action, the Examiner also rejected claims 1-7, 12, 19-24, 28-31 and 37-41 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,403,314 to Currier. Referring to FIG. 3 thereof, Currier discloses a connector member 32 having a first opening 36 adapted to receive a stabilizing rod and a second opening 40 adapted to receive a bone fastener. The first opening 36 extends through the connector member 32 in a first direction indicated by arrow 37. The second opening 40 extends through the connector member 32 in a second direction indicated by arrow 42. The connector member 32 includes top and bottom surfaces 46 and 48 (FIG. 4) when connected to the spinal column 10. The connector member 38

includes a mounting section 38 that has a side surface 50 that extends at an acute angle X to the top and bottom surfaces 46 and 48.

Independent claim 1, as amended, is unanticipated by Currier because the cited reference neither discloses nor suggests a bone fixation assembly including "a coupling element having an inner surface defining a first bore coaxial with a first longitudinal axis and a second bore coaxial with a second longitudinal axis, wherein said first and second longitudinal axes intersect and are in communication with one another." Clearly, Currier's two bores 37, 42 (FIG. 3) do not define axes that intersect one another. For these reasons, claim 1 is unanticipated by Currier and is otherwise allowable. Claims 2-7, 12, and 19-21 are unanticipated, *inter alia*, by virtue of their dependence from claim 1, which is unanticipated for the reasons set forth above.

Independent claim 22, as amended, is unanticipated by Currier because the cited reference neither discloses nor suggests a bone fixation assembly including a "coupling element having a U-shaped opening that extends from the upper end of said coupling element toward the lower end of said coupling element, wherein said U-shaped opening is adapted to receive a stabilizing rod." Clearly, Currier's connector member 32 does not have a "U-shaped opening that extends from the upper end of said coupling element toward the lower end" thereof. For these reasons, claim 22 is unanticipated by Currier and is otherwise allowable. Claims 23-24 are also unanticipated, *inter alia*, by virtue of their dependence from claim 22, which is unanticipated for the reasons set forth above.

Independent claim 28, as amended, is unanticipated by Currier because the cited reference neither discloses nor suggests a coupling element having "a U-shaped rod receiving

opening extending from said upper end toward said lower end of said coupling element." Independent claim 28 is also unanticipated by Currier because the cited reference neither discloses nor suggests a "coupling element having an inner surface defining said first and second bores and a seat adjacent said second bore at said lower end of said coupling element; and an anchoring element having a first end for insertion into bone and a head spaced from said first end, said head being in contact with said seat of said coupling element." Claims 29-31 are unanticipated, *inter alia*, by virtue of their dependence from claim 28, which is unanticipated for the reasons set forth above.

Independent claim 37, as amended, is unanticipated by Currier because the cited reference neither discloses nor suggests a coupling element including "a U-shaped opening that extends from the upper end of said coupling element toward the lower end of said coupling element, wherein said U-shaped opening is adapted to receive a stabilizing rod." Claims 38-41 are unanticipated, *inter alia*, by virtue of their dependence from claim 37, which is unanticipated for the reasons set forth above.

The Examiner also rejected claims 13-14 and 25-27 under 35 U.S.C. § 103(a) as being unpatentable over Morrison in view of U.S. Patent No. 6,280,442 to Barker et al. In response, Applicants respectfully assert that Barker does not overcome the deficiencies noted above in Morrison et al. Thus, claims 13-14 and 25-27 are unobvious over Morrison and Barker and are otherwise allowable.

The Examiner rejected claim 13 under 35 U.S.C. § 103(a) as being unpatentable over Morrison in view of U.S. Patent No. 5,554,157 to Errico. In response, Applicants respectfully assert that Errico does not overcome the

deficiencies noted above in Morrison. As such, claim 13 is unobvious over Morrison and Errico and is otherwise allowable.

The Examiner rejected claims 18 and 33 under 35 U.S.C. § 103(a) as being unpatentable over Morrison in view of U.S. Patent No. 5,725,527 to Bierdermann et al. In response, Applicants respectfully assert that Bierdermann does not overcome the deficiencies noted above in Morrison. As such, claims 18 and 33 are unobvious over Morrison and Bierdermann and are otherwise allowable.

Finally, the Examiner rejected claims 36 under 35 U.S.C. § 103(a) as being unpatentable over Morrison and U.S. Patent No. 5,474,551 to Finn et al. In response, Applicants respectfully assert that Finn does not overcome the deficiencies noted above in Morrison. As such, claim 36 is unobvious over Morrison and Finn and is otherwise allowable.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which she might have.

If there are any additional charges in connection with this requested Amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: August 11, 2004

Respectfully submitted,

By 

Michael J. Doherty

Registration No.: 40,592

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicant

507929\_1.DOC